REMARKS

Objection to the Specification

The Examiner has objected to the specification stating that the specification does not provide antecedent basis for the claimed subject matter. Specifically, the Office Action states that specification does not include proper antecedent basis for a repetition parameter that defines a number of pulses within a stimulation cycle "independent from one or several pulse frequency parameters." Office Action, page 2.

Applicant respectfully notes that the original application disclosed the claimed subject matter. Namely, the repetition parameter(s) and the frequency parameter(s) were originally described as distinct operational parameters of a neurostimulator. *See, e.g.*, original paragraph [0062]. However, solely for the purpose of expediting prosecution of the present application, Applicant has amended the specification to include language that provides direct antecedent basis for the claimed subject matter.

Accordingly, Applicant respectfully requests the Examiner to withdraw the objection.

Rejection under 35 U.S.C. § 103(a)

Claims 1, 4-5, 13, 16-18, 24, 26-28, and 30-31 are rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent Application Publication No. 2001/0007950 by North et al. (hereinafter "North") in view of U.S. 5,324,317 to Reiss (hereinafter "Reiss").

Claims 2-3, 14-15, 25, and 29 are rejected under 35 U.S.C. § 103(a) as being unpatentable over North in view of U.S. Patent No. 5,038,781 to Lynch (hereinafter "Lynch") in further view of Reiss.

Applicant notes that claims 1-18 are cancelled without prejudice. Accordingly, the rejection of these claims is now moot and is not addressed herein. Applicant reserves the right to pursue some or all of these claims in a continuing application.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to

combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the applied reference (or references when combined) must teach or suggest all the claim limitations. *See* MPEP § 2143. Applicant respectfully submits that the applied references do not satisfy these criteria.

The North and Reiss Combination

Currently pending claims 24, 26-27, 28 and 30-31 are rejected in view of the combination of North and Reiss.

Claim 24 recites:

> stimulating living tissue(s) using a substantially continuous set of pulses wherein the stimulating includes (i) successively selecting a stimulation set from the plurality of stimulation sets in a cyclical manner; (ii) generating a pulse according to the pulse characteristic of the selected stimulation set; and (iii) delivering the generated pulse to living tissue(s) through electrodes according to the electrode configuration of the selected stimulation set;
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> wherein the stimulating repeats the generating and delivering for the at least one of the plurality of stimulation sets according to the repetition parameter within each stimulation cycle independent from one or several frequency parameters associated with the plurality of stimulation sets.

Claim 28 recites:

> (i) successively selects a stimulation set from the plurality of stimulation sets in a cyclical manner;
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> (ii) loads the pulse characteristic into a pulse control associated with the pulse generator;
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> (iii) configures an output switch matrix according to the electrode configuration of the selected stimulation set;
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> (iv) causes the pulse generator to output at least one pulse after the loading and configuring, wherein the microprocessor causes the pulse generator to generate adjacent pulses according to a frequency parameter; and
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> (v) when the selected stimulation set is the at least one stimulation set associated with the repetition parameter, repeating (iv) according to the repetition parameter within a stimulation cycle independent from the frequency parameter.

Applicant respectfully notes that North merely discloses conventional stimulation parameters and does not teach or suggest a "repetition parameter" as specifically claimed.

In the Office Action, the rejection of these claims states that "Reiss teaches of an interferential stimulation that comprises a repetition parameter." The rejection cites col. 1,

lines 62-68 and col. 2, lines 1-16 of Reiss to support this proposition. *See* Office Action, page 2.

The portion of Reiss upon which the rejection relies is as follows:

> The interferential stimulator includes a mode control to permit changing the sequence of stimulation to prevent accommodation to the unit and to enable a number of alternatives to be evaluated to find the most effective pain relief. In the first mode, the unit is operated in a continuous manner at one set of frequencies. In a second mode the stimulator operates at a set pulse rate for a short period, such as about one second, drops to a much lower pulse rate, such as about 50% for a short period, such as about one second, then **repeats**. In a third mode, the stimulator operates at a set pulse rate for a period of from about 1 to 15 seconds (preferably about 8 seconds), drops to a much lower rate, typically about 50%, for from about 1 to 15 seconds (preferably the same length as the first period), then **repeats**. In a fourth mode, the stimulator operates at a set pulse rate for a period of from about 1 to 15 seconds (preferably about 10 seconds) then slowly drops to a much lower pulse rate, typically about 50% of the set value over a period of from about 1 to 15 seconds (preferably the same as the initial operation period), then **repeats**. These periods, degree of decrease between sequences and the initial set pulse rate may be varied, where suitable, if desired.
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> Col. 1, lines 62-68 and col. 2, lines 1-16 (emphasis added).

As seen, Reiss merely states that stimulation occurs at a predetermined pulse rate for a given period of time and then the pulse rate is lowered for another amount of time. The process is repeated by again starting with the high pulse rate and changing to the lower pulse rate. Thus, Reiss merely discloses repeatedly switching back and forth between a high rate of stimulation and a lower rate of stimulation. However, there is no disclosure of a "repetition parameter" in Reiss that controls the repetition of the stimulation pulses in Reiss.

Additionally, the claimed "repetition parameter" controls the repetition of pulses for a given stimulation set within a "stimulation cycle." As specifically claimed, the stimulation cycle is defined by the successive selection of stimulation sets. One of the selected stimulation sets is used to generate multiple pulses within the stimulation cycle according to the repetition parameter. Specifically, in regard to claim 24, the claimed subject matter requires "the stimulating repeats the generating and delivering for the at least one of the plurality of stimulation sets according to the repetition parameter within each stimulation cycle." Similarly, in regard to claim 28, the repetition of outputting a pulse (according to a pulse loaded pulse characteristic and switch matrix configuration) occurs "according to the

repetition parameter within a stimulation cycle." There are no stimulation cycles (as defined by cycling through a plurality of stimulation sets) within Reiss as claimed and, hence, there is no repetition parameter that controls repetition of a pulse for a given stimulation set within a stimulation cycle.

Therefore, North and Reiss (either individually or in combination) do not teach or suggest each and every limitation of claims 24 and 28. A prima facie case of obviousness has not been established for these claims. Claims 26-27 and 30-31 respectively depend from claims 24 and 28 and, hence, a prima facie case of obviousness has not been established for claims 26-27 and 30-31.

The North, Reiss, and Lynch Combination

Currently pending claims 25 and 29 are rejected over the combination of North, Reiss, and Lynch. Claims 25 and 29 respectively depend from base claims 24 and 28 and, hence, inherit all limitations of their base claim.

For the reasons discussed above, the combination of North and Reiss fails to teach or suggest the "repetition parameter" as recited.

Lynch is merely directed to a functional electro-stimulation (FES) system that verifies stimulation parameters using parity codes. *See* col. 13, lines 30-44 of Lynch. Lynch does not teach or suggest a repetition parameter as claimed.

Thus, the applied references (either individually or in combination) do not teach or suggest each and every limitation of claims 25 and 29. A prima facie case of obviousness has not been established for claims 25 and 29.

Conclusion

Applicant respectfully submits that the application is in condition for allowance and requests the Examiner to pass the application to issue. If the Examiner believes that a telephone call would be helpful in resolving any remaining issues, the Examiner is invited to call the attorney listed below.

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Respectfully submitted,

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